Paper No. 41

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALEJANDRO DEE and CHARLES GRADLE

Appeal No. 2002-1644
Application No. 08/602,498

ON BRIEF

Before WINTERS, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 14-16 and 21-24 which are all the claims pending in the application.[1]

Claims 14 and 21 are illustrative of the subject matter on appeal and are reproduced below:

14. A method of preventing mastitis in a dairy animal, comprising the step of topically applying an antimicrobial composition to the teats of the animal, the composition consisting essentially of (1) from about 60% to about 95% of a lipophilic polar solvent selected from the group consisting of propylene glycol, ethylene glycol, glycerol, and isopropanol, by weight of the composition, and (2) at least two C_8 to

[1] We note that the Appendix of claims on appeal attached to the Brief, includes claims 17-20. However, as appellants explain (Brief, page 2), these claims together with claims 1-7 and 9-12 "were cancelled pursuant to a restriction requirement and are currently pending in U.S. Application Serial No. 09/586,860…." Accordingly, we have not considered claims 17-20 as part of this appeal.

C_{14} fatty acids in a total amount of from about 0.5% to about 5% by weight of the composition.

21. A method of preventing mastitis in a dairy animal, comprising the step of topically applying an antimicrobial composition to the teats of the animal, the composition comprising (1) from about 60% to about 95% of a lipophilic polar solvent selected from the group consisting of propylene glycol, ethylene glycol, glycerol, and isopropanol, by weight of the composition, and (2) at least one C_8 to C_{14} fatty acid in an amount of from about 0.5% to about 5% by weight of the composition.

The references relied upon by the examiner are:

Kabara	EP 0 530 861 A2	Mar. 10, 1993

The examiner also relies on evidence of the commercial sale of a product described as DX-206. It is, however, unclear from the Answer and the Final Rejection dated August 17, 2000 exactly what evidence is relied upon to support this finding. In this regard, we note that appellants' Brief includes an Information Disclosure Statement (Tab 4) describing the events surrounding the sale of DX-206, a letter dated November 2, 1994 (Tab F) highlighting the intent to market "a new Post Dip with some unique properties", a "Material Safety Data Sheet" (Tab G) for DX-206, an invoice (Tab K) dated January 31, 1995 recording the sale of DX-206 to Northside Dairy Supply, and records of the sale of DX-206 (Tab N). Nevertheless, we note that "[a]ppellants admit that the topical application of DX-206 to the teats of dairy cows to prevent mastitis is covered by all the claims on appeal. Thus, should the on-sale issue be decided adversely to [a]ppellants, [a]ppellants agree that the claims on appeal are not patentable as presently drafted." Brief, bridging paragraph, pages 4-5. Accordingly, we have reviewed the evidence noted above, together with appellants' admission and the

statements made in the Brief and the Declarations of Gardner (Tab 2); Dee (Tab 3); Meisters (Tab 6); and Wilkins (Tab 7).

GROUNDS OF REJECTION

Claims 14-16 and 21-24 stand rejected under 35 U.S.C. § 102(b) in view of the commercial sale of DX-206.

Claims 14-16 and 21-24 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as being unpatentable over Kabara.

We affirm the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Kabara. We reverse all other grounds of rejection.

DISCUSSION

THE REJECTIONS UNDER 35 U.S.C. § 102:

Commercial Sale:

According to the examiner (Final Rejection, page 2),

> [t]he record in this case shows DX-206 is the composition of the instant invention to be applied as a teat dip to dairy cows, for the purpose of reducing, ameliorating and preventing mastitis-the instant method calls for applying to the teats; the step immediately envisioned by one of ordinary skill in dairy husbandry. This product was in fact sold to Dr. Gardener and Mr. Anderson, thus constituting a commercial sale.

In response, appellants rely upon Pfaff v. Wells Elecs., Inc., 535 U.S. 55, 48 USPQ2d 1641 (1998), and argue that the sale of DX-206 fails to meet either part of the two-part test set forth in Pfaff. Brief, page 5. According to Pfaff the "on-sale" bar applies if (1) the product is the subject of a commercial offer for sale, and (2) the invention is ready for patenting. Id. 535 U.S. at 57, 48

USPQ2d at 1646-47. As the court explained (id. 535 U.S. at 57, 48 USPQ2d at 1647), the second part of the test may be satisfied in at least two ways: (1) by proof of reduction to practice before the critical date[2]; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.

According to appellants (Brief, page 5, emphasis removed), the sale of DX-206 fails to meet the first part of the Pfaff test because "DX-206 was not the subject of commercial sales prior to the critical date … [instead the sales] were primarily for an experimental purpose." In addition, appellants argue (id.) that the second part of the Pfaff test does not apply in this case because "the claimed invention was not 'ready for patenting' … when the above-noted sales were made, or at any time prior to the critical date."

With reference to the Gardner and Dee Declarations, appellants' argue (Brief, page 6), "the sales by Babson[3] of DX-206 to Dr. Gardner and Mr. Anderson prior to February 20, 1995[4], were for experimental purposes, as were the sales by Dr. Gardner and Mr. Anderson of DX-206 to certain of Dr. Gardner's veterinary clients." According to the Dee Declaration (paragraphs 2-6) the DX-206 formulation was under development up until "December 6-7, 1994." As Dee

[2] The instant application was filed on February 20, 1996, accordingly, the critical date for purposes of the "on-sale" bar is one year prior to the filing date, specifically February 20, 1995.

[3] The instant application "is assigned to Babson Bros. Co. (Babson), which on March 9, 1999 was acquired by Gea AK Aktiengesellschaft of Germany and is now known as Westfalia-Surge, Inc." Brief, page 1.

[4] Accordingly, the sales were made before the critical date "one year prior to the actual filing date of the instant application."

explains (id., paragraph 7), "[a]lthough this product performed satisfactorily in laboratory tests, I did not know how it would perform in actual use on dairy animals. As a result, a quantity of DX-206 was provided to Dr. Gardner on January 31, 1995 for field testing by his clients in their herds." Dee emphasizes (id., paragraph 8), "[a]t the time it was sent to Dr. Gardner, the DX-206 formulation was not a commercial product. It had undergone no field testing, and had not been subjected to protocol testing using control animals to determine its efficacy in a more quantitative way." In addition, Dee declares (id., paragraph 10):

> The DX-206 formulation was changed based on the results of Dr. Gardner's field testing. For example, in October 1995, based on complaints from some of Dr. Gardner's clients that DX-206 did not work well in teat dip sprayers, more water was added to the formulation to make the product easier to spray. Wintergreen was also added at this time to improve the odor of the product.
>
> The Gardner Declaration confirms the statements made by Dee.

According to Gardner (id., paragraph 8), "[a]lthough DX-206 had performed well in laboratory tests, such performance was not indicative of how the product would perform in the field, under extreme conditions and with actual dairy animals." In addition Gardner declares (id., paragraph 16):

> Before DX-206 was field tested by certain of my clients under my supervision, I did not know whether it would work for its intended purpose. In fact, although many of my clients were quite satisfied with the DX-206 formulation, others … decided not to use DX-206 based on their experience in the field test.

Gardner also declares (id., pagaraph 9), "varying amounts of DX-206 [were sold] to my herd health clients, asking them to try the product for test purposes."

According to Gardner (id., paragraph 10), the product was sold to the dairyman because,

> [i]f a test product is provided to the dairyman at no cost, or at a substantially reduced cost compared to the product the dairyman is currently using, the dairyman will have a tendency to overstate the effectiveness of the test product in an effort to obtain a lower cost or free test product. If the test product is provided at a price or is substantially near the projected retail price, an unbiased evaluation of the product from the dairyman is usually obtained.

As set forth in EZ Dock Inc. v. Schafer Systems Inc., 276 F. 3d 1347, 1352, 61 USPQ2d 1289, 1292 (CAFC 2002), citations omitted,

> an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention – even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially. … Experimentation evidence includes "tests needed to convince [the inventor] that the invention is capable of performing its intended purpose in its intended environment."

Here as in EZ Dock, 276 F. 3d at 1352, 61 USPQ2d at 1292-93, the evidence demonstrates that the full market price was not paid for the product during testing. Gardner declares (Gardner Declaration, paragraph 12) that he "regularly monitored the efficacy of DX-206 via personal visits and phone conversations to … [his] clients over at least a period of several months" and reported any problems to Babson. As set forth in EZ Dock, 276 F.3d at 1353, 61 USPQ2d at 1293 (citations omitted), "this court has often consulted evidence of monitoring to discern the distinction between experimental and commercial sales."

Based on the evidence on this record, it is our opinion, that the inventors were working to detect and correct flaws in their invention during the field trials. Cf. EZ Dock, 276 F.3d at 1353, 61 USPQ2d at 1293. Accordingly, in our opinion

the "sales" were for experimental purposes to further refine the claimed invention. Therefore, we find that the examiner has not provided the evidence necessary to meet the first part of the Pfaff test. Accordingly, we do not consider the second part of the Pfaff test. Having found that the "sales" fall within the experimental-use exception of 35 U.S.C. § 102(b), we reverse the rejection of claims 14-16 and 21-24 under 35 U.S.C. § 102(b) in view of the commercial sale of DX-206.

Kabara:

"Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim." Gechter v. Davidson, 116 F.3d 1454, 1457, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). Furthermore, an anticipatory reference must unequivocally disclose the claimed method or direct those skilled in the art to the method without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 35 U.S.C. §103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 35 U.S.C. §102, anticipation rejection. See In re Arkley, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972).

As appellants explain (Brief, page 13),

> [w]hile it is disclosed that certain of the compositions can be used as bovine teat dips, … [Kabara] discloses that its various

> compositions can be used in … (1) preservatives in food stuffs, (2) cosmetic formulations, (3) pharmaceutical formulations (topical, parenteral, intramuscular, and intravenous), and (4) veterinary formulations, such as teat dips, eye medications, and ear medications."

In addition, appellants point out (Brief, page 14), Kabara discloses that propylene glycol "should be used at any suitable level, with 5-60% by weight being preferred, 10-30% being more preferred, and 20-25% being most preferred." Based on this disclosure in Kabara, appellants argue (id.), "[s]uch a broad statement, which can relate to such diverse compositions as cosmetics and pharmaceutical formulations, does not provide a teaching with respect to teat dip compositions." Instead, appellants argue (Brief, pages 14-15id.), one interested in the art of teat dips, would look to Kabara's exemplified teat dips (examples 2-4) that contain significantly less propylene glycol than required for the compositions of the claimed methods. Upon review of the facts in evidence, we are compelled to agree with appellants. Accordingly, we reverse the rejection of claims 14-16 and 21-24 under 35 U.S.C. § 102(b) as anticipated by Kabara.

THE REJECTION UNDER 35 U.S.C. § 103 over Kabara:

According to appellants (Brief, page 4), claims 14-16 will stand or fall separately from claims 21-24. Therefore, we will limit our discussion to representative independent claims 14 and 21. Claims 5 and 16 will stand or fall together with claim 14 and claims 22-24 will stand or fall together with claim 21. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Answer, page 4), "[i]t would have been obvious for one of ordinary skill in the art to [m]odify [Kabara to provide the] …

required amount of propylene glycol solvent in order to provide optimum efficacy as an antimircobial, freeze protected and non-irritating teat dip. Thus, added ingredients of Kabara do not alter these essential characteristics of the methods of use of the compositions."

Claim 14:

In response to the rejection, appellants argue (Brief, page 13), "the 'consisting essentially of' language in claims 14 through 16 renders those claims clearly outside the disclosure of [Kabara] …." In this regard, appellants point out (Brief, page 18) that Kabara "use[s] a fatty acid ester as their primary antimicrobial agent, with the addition of other components, such as fatty acids, to improve the antimicrobial activity of the compositions." In contrast to Kabara, appellants' claim 14 does not require the presence of a fatty acid ester.

With reference to the Meister Declaration (Brief, page 19), appellants explain that Meisters prepared four compositions, (1) the composition of Kabara's example 3, (2) the composition of Kabara's example 3, modified to contain 30% propylene glycol, (3) the composition of Kabara's example 3, modified to contain 60% propylene glycol, and (4) the composition of the present invention. Meisters declares (Meisters Declaration, paragraph 8) that in a "cold weather stability" test all of the formulations based on example 3 of Kabara froze at 0°F, while those of the instant invention did not freeze at 0°F. Therefore, Meisters concludes (id., paragraph 9), "[t]he formulation of the claimed invention is therefore much more stable at low temperature than the formulations of Example 3 of … [Kabara]." In addition, Meisters concludes (id., paragraph 10),

> the stability of the compositions of the present invention cannot be solely attributed to the amount of propylene glycol in the composition, because the composition of Example 3 modified to contain 60% propylene glycol froze at 0°F, while a composition of the present invention having 60% propylene glycol will not freeze at 0°F.

It is well settled that "[t]he word 'essentially' [in 'consisting essentially of'] opens the claims to the inclusion of ingredients which would not materially affect the basic and novel characteristics of appellant's compositions as defined in the balance of the claim." In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963) (emphasis in original). In our opinion, the Meisters Declaration demonstrates that Kabara includes ingredients that affect the basic and novel characteristics of appellants' composition, and thereby would affect the claimed method of using the composition. Therefore, we cannot agree with the examiner's position (Answer, page 5), "there is no preclusion of the fatty ester, as appellant [sic] claims."

For the foregoing reasons we reverse the rejection of claims 14-16 under 35 U.S.C. § 103 as being unpatentable over Kabara.

Claim 21:

Claim 21 stands on a different footing, in that it does not use the transitional phrase "consisting essentially of", but instead uses the transitional term "comprising". Accordingly, we are not persuaded by the Meister declaration, particularly since there is no limitation in the claimed method regarding the compositions performance at 0°F. Similarly, the evidence of commercial success set forth in the Wilkins Declaration does not persuade us. According to Wilkins (Wilkins Declaration, paragraph 4), the composition is

"mainly a 'niche' product, sold for use in cold weather." As set forth in In re Tiffin, 448 F.2d 791, 792, 171 USPQ 294, 294 (CCPA 1971), evidence of secondary considerations such as commercial success must be commensurate in scope with the claims under review. Since claim 21 does not limit the method to "cold weather" applications, the evidence of commercial success is not commensurate in scope with claim 21.

Kabara teach a topical antimicrobial pharmaceutical composition for use as a teat dip, comprising (1) a glycerol fatty acid ester, (2) a mixture of two C_6-C_{18} fatty acids and (3) a pharmaceutically acceptable carrier. See Abstract and page 3, lines 51-52. At page 5, Kabara teaches that a preferred carrier generally includes, inter alia, an alcohol such as propylene glycol. According to Kabara (page 6, lines 4-6), "[t]he alcohols discussed above may be employed in the compositions and methods of the present invention at any suitable level. In a preferred embodiment, they are present at a level of about 5 to about 60%…."

With regard to the claimed range and the range taught by Kabara, we recognize that a range that overlaps a range disclosed by the prior art may be patentable if appellants can show criticality in the claimed range by evidence of unexpected results. In re Wertheim, 541 F.2d 257, 267, 191 USPQ 90, 100 (CCPA 1976). However, as discussed above, we are not persuaded by appellants' evidence of unexpected results or commercial success.

For the foregoing reasons, we affirm the rejection of claim 21 under 35 U.S.C. § 103 as being unpatentable over Kabara. As set forth above claims 22-24 fall together with claim 21.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

Sherman D. Winters Administrative Patent Judge	)
Donald E. Adams Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Demetra J. Mills Administrative Patent Judge	)

LATHROP & CLARK LLP
740 REGENT STREET SUITE 400
P.O. BOX 1507
MADISON WI 53701-1507